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Advancements in Individualized Drug Formulations

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ABSTRACT

The advent of personalized medicine (PM) has catalyzed a shift from traditional "one-size-fits-all" approaches to individualized therapeutic strategies that address genetic, physiological, and lifestyle differences among patients. Fixed-dose pharmaceutical products often fail to meet the diverse needs of patient populations, resulting in significant adverse effects and suboptimal outcomes. Innovations such as 3D printing technologies offer transformative solutions by enabling rapid, cost-effective, and tailored drug formulations. Key advances include complex drug delivery systems, pharmacogenomics integration, patient-centric design, and emerging concepts like 4D printing. Despite substantial progress, significant regulatory, ethical, and economic challenges remain. Personalized drug formulation holds immense potential for improving treatment adherence, efficacy, and healthcare economics, but requires careful navigation of technical, ethical, and regulatory landscapes to ensure equitable access and patient safety. The future of individualized drug therapy lies in interdisciplinary collaboration, technological innovation, and dynamic regulatory frameworks that support on-demand, patient-specific treatments.

Keywords: Personalized Medicine; 3D Printing; Individualized Drug Formulation; Pharmacogenomics; Fixed-Dose Combinations; Patient-Centric Design

INTRODUCTION

Personalized Medicine (PM) involves customizing medical treatments to fit individual patient needs and characteristics. Also known as precise or individualized medicine, PM abandons the "one-size-fits-all" approach in favor of administering the "right drug" in the "right quantity" to the "right patient" at the "right time." The foundation of PM lies in the understanding that each individual's genome affects their response to drugs, foods, diets, and lifestyle choices, all essential for effective disease management. Consequently, PM focuses on diagnosing, preventing, and treating health conditions based on genetic differences among individuals. Fixed-dose products, limited to narrow therapeutic scopes, often fail to achieve effective outcomes for many patients, contributing to 75–85% adverse effects from non-tailored therapies. Patient drug responses can vary significantly; some may achieve desired results, while others face side effects or inadequate drug levels. This risk escalates for those with unique biopharmaceutical responses. Additionally, mass-manufactured drug doses can exacerbate toxic range issues across patient populations, as responses to solid doses can differ by a factor of 10–30. Factors like thin gastrointestinal tracts or limited absorptive areas can hinder the effectiveness of standard solid dosage forms, often requiring additional modifications for proper administration. 3D Printing, or additive manufacturing, refers to creating three-dimensional objects by layering materials from digital files. This process encompasses various techniques, such as fused deposition modelling and selective laser sintering. In the pharmaceutical sector, one common method involves extruding melted or dissolved thermoplastic materials through a nozzle to form layers, with each new layer being added on top of the previous one as the building plate is gradually repositioned [1, 2].

Historical Background

Commercially available drugs are usually mass produced as fixed-dose products intended for the general population. For solid dosage forms, these include tablets, capsules, granules, and pellets. Usually, when a

fixed-dose drug product is developed, analytical techniques are used to study the drug release properties, following which in vivo studies are conducted to ascertain their efficacy. In this manner, the successes and failures of drug formulations are systematically studied, leading to the discovery of the best products for mass production. For chronic treatments, dosage strengths of drugs considered useful for initial treatment are fixed only for the majority of the population. Individualization of drug formulations has been a challenge in the drug development process, which has led to an appreciable number of drug dose-based medications being available in the market. Each of these dose strengths is targeted towards specific individuals with varied dosing requirements, and thus patients belonging to different populations can receive the best treatment from the same drug molecule. At a fixed dose of 12 mg of fluoxetine, 78% of patients receiving this dose had a positive outcome, whereas the rest had inadequate or no therapeutic effects. On the other hand, at a dose of 5 mg, 66% of patients experienced a favorable outcome. Interestingly, the 12 mg adult tablet was subsequently modified to a 10 mg hard capsule formulation targeting adolescents but had no specific lower dose formulations or other dosage forms for pediatric patients. From the above incidence, it is evident that the therapeutic window of a marketed daily fixed-dose drug product was targeted to only a fraction of the target population, which led to many patients receiving undesired treatment or none at all. There are many other instances where drugs initially developed for adult formulations are not specific to populations having lower neuromuscular coordination and body mass, which has led to treating such patients with excipients non-specific to them while there are patient safety concerns. The inflexibility of marketed fixed-dose products puts at risk their efficacy towards certain patients [3, 4].

Current Trends in Drug Formulation

The world today is heading towards personalization of every product. Individualized formulations of drugs for meeting the specific need with respect to the disease and its physiology have been in demand. The current drug formulations and dosages are common for all the patients. But the physiology of every individual is unique, which implies that the overall structure of the diseases and its biochemistry differs among individuals. This calls for the design of individualized drug dosage forms for treating several ailments affecting mankind on earth. This posed a challenge to the scientists to come up with a viable strategy to formulate the drugs that can be used with an individualized approach. A further challenge was to produce these individualized formulations rapidly, economically, and in large scale. To address these challenges, an entirely new concept of "personalized" or "individualized medicine" has emerged in research and industry. Rapid advancement in pharmaceutical science and technology has opened the path for a different way of drug formulation that also meets the need for mass production of individualized formulations. The recent advancements in the field of robotics and allied technologies have made it possible to develop "Three-Dimensional Printing (3DP)" where the drug formulations can be printed similar to printers locally, rapidly, and economically. The application of 3DP technology in the pharmaceutical sector can be grouped into two domains: (1) the application of 3D printing in the medical field—prosthetics, models, scaffolds, etc.; (2) the application of 3D printing in the pharmaceutical where dosage forms of pharmaceuticals are printed. 3D printing shows great promise in the field of formulation, dosage, and drug delivery, not only for shaping the drugs but also with better control over release rate and route of administration [5, 6].

Personalized Medicine Overview

Personalized medicine (PM) refers to customization of medical treatment to the needs, characteristics, and preferences of individual patients. This entails amending the conventional "one-size-fits-all" medical practice to the "right drug" in its "right quantity" for the "right patient" at the "right time." PM is based on the fact that each individual's genome specifies their response, including adverse effects and allergic reactions, to specific drugs, diets, and lifestyle activities. Consequently, this helps physicians ascertain the "right drug" and its "right quantity" to fit the "right patient" and a time at which the drug would elicit the "right response." This medical approach is referred to as PM, which can be adopted in the diagnosis, prevention, and treatment of health conditions based on inter-individual genetic differences. The prevalence of adverse effects due to untailored therapy is 75–85%. This is because patients' responses to drug doses vary widely; as a result, some populations may experience the desired therapeutic outcome, whereas others may experience adverse effects or have inadequate plasma drug levels for therapeutic effects. Moreover, responses to mass-manufactured discrete drug doses can vary 10–30 fold or more among the majority of patients. On account of this, there is a pressing need for individualized therapeutic agents wherein a particular drug dose and/or dosage form can be tailored to the patient's specific

response. The major PM approach currently under research is individualizing drug formulations. In this regard, a paradigm shift is envisaged wherein 3D printing of medicines would be done on demand at the pharmacy or even clinical settings using bio-inks prepared from APIs and excipients suitable for a particular patient. Consequently, 3D printing is touted to have a disruptive impact on the pharmaceutical industry in terms of changing current conventional paradigms [7, 8].

Technological Innovations

In recent years, advancements in applied pharmacy have led to the emergence of complex drugs, enhancing existing medicinal products through innovation. Oral dosage forms that enable long and sustained release of active pharmaceutical ingredients (APIs) could revolutionize care and therapy effectiveness. Fixed-dose combinations (FDCs), which are formulations containing multiple active substances in a fixed ratio, can improve both efficacy and safety while lowering costs when the ingredients are complementary. Common FDC types include monolithic, multiple-layer, and multiarticulate systems. Current leading pharmaceutical manufacturing techniques incorporate combined wet and dry granulation of powders into beads coated with polymeric materials. Hot-melt extrusion (HME) facilitates filament production and capsule creation using die-injection systems for implantable forms. Compression of bilayered tablets into oval shapes allows for subsequent coatings and surface treatments in continuous production. A promising area for FDC development is 3D printing (3DP), which is gaining traction in the industry for creating polypills, solid dosage forms with several APIs in fixed ratios. This method has the potential to mitigate patient non-compliance with polypharmacy by producing single polypills for multiple medications. The rise of personalized medicine underscores the importance of 3D printing in making complex and tailored solid dosage forms. A notable trend in 3DP focuses on versatile materials that evolve over time, leading to the concept of "4D printing." This approach addresses many limitations of conventional FDCs, enabling adjustable dosages and enhancing bioavailability and compatibility of ingredients. Recent reviews have highlighted the smart pharmacotherapy concept using digital medicines created via 4D printing. Moreover, expandable gastric retention systems for FDCs can be developed through self-folding or unfolding techniques. In 2023, researchers introduced a method to tailor the drug release of FDCs to individual pH levels in patients with gastroenterological issues, marking a potential technological revolution in fixed-dose combination drugs once regulatory barriers to 4D printing are surmounted [9, 10].

Pharmacogenomics

A molecular profiling effort is underway to create a universal predictive algorithm for optimizing medication selection and dosing for antidepressants, based on various genomic and non-genomic patient characteristics. Variability in clinical responses to standard therapeutic dosages was noted as early as the 1950s, including a 1956 link between the antithyroid drug propylthiouracil and the severe side effect agranulocytosis due to a drug metabolism enzyme variant. In the 1960s, two mutations of an enzyme linked to idiosyncratic drug reactions to NSAID sulfanilamide were discovered. The so-called poor metabolizer phenotype associated with arylamine N-acetyltransferase polymorphisms was identified in 1970. This led to discoveries of polymorphisms in drug metabolism and target variations affecting thousands of drugs across humans and animal models. Efforts towards pharmacogenomic-guided drug therapy involved scrutinizing drug-gene associations through gene-polymorphism-phenotype-drug-response analyses. Many widely prescribed drugs feature pharmacogenomic biomedical literature and guidelines for diagnostics assessing drug metabolism. Although clinicians generally agree on the potential for personalized therapy tailored to genetic profiles, it is viewed as years away due to various reasons. Current pharmacogenomic tests have centered on variants disrupting protein function, primarily analyzing genes with low-frequency functional variants, while the consequences of these variants regarding commonly prescribed drugs with major side effects were often overlooked. The impact of well-validated pharmacogenes was limited for drug response, prompting ongoing efforts to investigate rare exonic and splice-region variants in drug-gene relationships through genome-wide sequencing. An expert-driven catalog of pharmacogenomic biomarkers focusing on genes with known validated variants has been constructed. This catalog aids in examining a specific pharmacogenomic candidate's expression and function across drugs. The aim is to adapt this framework for other widely used medicines and incorporate validated pharmacogenes into routine pharmacogenomic profiling. Non-genomic variables are included in the predictive algorithm, which is being validated. The objective is to develop genetic and non-genomic profiling alongside a predictive algorithm for broader classes of drug-response interactions. Adverse drug reactions, a common complication in therapies, occur in 7-12% of hospitalized patients,

frequently stemming from drug-drug interactions that hinder drug metabolism, one of the twelve primary drug action mechanisms [11, 12].

Regulatory Challenges

While advances in technology are surely fueling improved efficacy and safety of the medicines, they are also multiplying the complexities in developing, manufacturing, and testing those medicines. Currently, biopharmaceuticals are considered advanced medicines. There are numerous drugs in the market which are complex biologics and are already in advanced dosage forms and are a part of parenteral development. Complex injectables are formidably challenging for the development and approval process as they often involve multi-unit operations and skilled human resources handling different unit operations. In the case of a generic product, there is trouble from selection of a suitable API and excipients, understanding the complexities of the manufacturing processes involved, construction of a dedicated production facility complying with cGMP, identifying unique or new characterization techniques, leveraging sophisticated equipment etc. Even after accomplishment of the entire que on development and manufacturing, regulatory submission stands as a major gate to entry. Science and Technology have now proliferated into medicines which go on working throughout a human life and at times in ill-formed journeys of the heart and nervous system. Knowledge-based inventions, mathematical inputs, and docking-based designs have allowed drafting firstly, microbiologics, anticancer, vaccine type biologics and now, recombinant proteins. The horizon of biopharmaceuticals is now getting longer with the birth of drug-device combination products. Particle engineering, chemical-immunological conjugation technologies, conjugation of even with metal, polymer and small molecules, co-extrusion technologies are flooding the markets with numerous differently structured big injection drugs. New medications as defined by well-formed structures emanating from well-established scientific principles and knowledge and tested by widely practiced proven methodologies are becoming complex [13, 14].

Focus on Patient Needs and Experiences

Personalisation of medicinal products poses significant healthcare challenges, focusing on tailored formulations and testing strategies for drug combinations under regulatory compliance. Olanzapine extended-release orally dissolving films (ODx) exemplify patient-centric designs, with efficacy and safety profiles comparable to traditional forms, yet superior adherence and preference. The films dissolve into a clear solution within 5 minutes, but taste perception post-dissolution can affect acceptability, necessitating strategies to mask unpleasant flavors. Furthermore, packaging plays a crucial role in usability; moisture-resistant packaging that is difficult for older patients to open may hinder ODx acceptance. Multi-particulate dosage forms, comprising mini-tablets or pellets in capsules or tablets, are promising for personalized treatments. For pediatric patients, dose adaptation, such as using pellet amounts based on weight, is advantageous, though adherence impacts remain untested. Exploring whether the acceptability of mini-tablets compared to syrups influences adherence could prove valuable. In the realm of topical treatments, a wide array of vehicles exists, including ointments, creams, gels, and patches, each possessing distinct mechanical and sensory properties that affect patient satisfaction and treatment compliance. Innovations in these treatments arise not only from new drug discoveries but also through reformulating existing vehicles to enhance administration, bioavailability, and ease of use [15, 16].

Ethical Considerations

The emergence of individualized drug formulation technology holds potential for enhancing patient care while introducing new ethical concerns. These personalized formulations, based on easily interpreted patient biological profiles, are nearing realization. Nonetheless, the excitement is tempered by awareness of the risks and potential harm, such as the possibility of worsening health disparities through misuse. Can this technology exacerbate existing inequities? Addressing these questions requires a robust approach to ethical issues. Consumer perspectives indicate that dosage form choice correlates with physician preferences; doctors desire more patient information regarding drug characteristics. Notably, women prefer tablets, while men lean towards liquids. Drug design impacts adherence differently across medication settings, yet predictions for individualized drug products remain poor. A slight uptick in personalized formulation preparation was noted among healthcare professionals and consumers before the pandemic. The coronavirus pandemic and the rise of telehealth have amplified the need for individualized drug product design to enhance treatment adherence and ensure safety through proper dosing. To tackle quality discrepancies in drug products, further assessments and testing regulations should be considered for various product types and clinical scenarios. The science and technology of drug development are

evolving, revealing opportunities for tailored drug preparation. However, as with all biotechnological advancements, the potential for misuse poses serious risks. While the benefits of individualized drugs are significant, they are accompanied by ethical dilemmas practitioners must thoughtfully navigate before crafting such products [17, 18].

Economic Impacts

The well-publicized 25-billion-dollar Merck HCV franchise was generated from the very marginal 2% improvement over standard therapy afor in the formulation of raid-f IMO. With regards to individualized formulations, on the whole, the economic forces that favor larger volume applications are strong. For example, if the current 200 patients and 50-100% benefits to existing drugs for existing patients, building off of existing biological/formulation tools, mean there are no net costs and clear social benefit. The costs of access on the 200 patients 100s of opportunities are modest at 10 million dollar or so for a national expert center structure, using existing expertise. Thus, this benefit of 25 billion, or southerly order of magnitude with 5-billion-dollar costs on biotechs production costs, to address moving to 20,000 could be small, or about equal. However, it is important to note that the profit motive is potentially problematic. Over-inflation of prices and exclusivity does and will cause very large side effects on product development in the US system. The economic benefits of drug reformulation are substantial. A conservative Australian estimate is for Sovaldi; single agent oral dosage forms were introduced on the 648 million dollar per annum and oral combination formulation off patent is on 194 million dollar per annum. Open label switching studies commonly find 90% take up; compliance becomes very high and drug half-lives over 12 hours on an approximate expense of 500 million dollar on post-market reformulation job. The new formulation drug delivery system euro dollars (2-3% worldwide) need to be carefully generated. The economic benefits to the market are very substantial; documentation of the costs of care with the infusion prod/pat was 120% higher and treatments per annum were reduced from 32 to 24. In Australia on costs of materials the net savings will be millions compared to the original products. By virtue of large endpoint changes on drug formulation, patent extension or insurance reimbursement, rus became dollar million industries. Intravenous administration is currently paid for across 300-million-dollar markets here. The introduction costs on switching include compliance estimation of health service providers, patient education versus social acceptance for drug formulations as significant initial formulation delivery had historical 30-150% care costs on hospital admissions [19, 20].

Future Directions

In the past decades, 3D printing technologies have attracted widespread attention within the pharmaceutical community and the most recent inclusion of 3D printing in the FDA guidance emphasizing the importance of PM formulations and prospectively advanced technology have cemented its pivotal role in the pharmaceutical landscape. Much of the published work has reviewed and critically evaluated recent advances using 3D printing in dosage forms designs and preparation targeting at the immediate, altered, pulsatile, and controlled release profiles, along with complex multi-drug composition profiles, stabilizations of drug/prodrug, production of 3D printed drug-loaded implants and scaffolds for emerging treatments. 3D drug printer models and cost-effective printing commenced in the academic laboratories have also transitioned into commercial products targeting larger clientele. More recently, there was an urgent need to expand the discussion of drug printing beyond the laboratory setting. On-site printing will require a collaborative effort among regulators, researchers, and clinicians to provide regulations to ensure the safety and efficacy of 3D printed drugs. However, this will require a significant rethinking of the feasibility and regulation of the dosing and specification of printed drugs. 3D printing can offer potential in achieving flexibility of doses according to patient needs. One major population group that calls for dose flexibility is the pediatric group in which the therapeutic dose varies according to the age and body weight of children. Many antiparasitic drugs, antibiotics and antiviral drugs can be obtained in the form of pediatric syrup but these formulations are not widely used for systemic anticancer agents, which usually come in the formulation of tablets or capsules. Various dosage forms mentioned above can be adequately modified using 3D printers to dispense the best dose for patients. In ODF formulations, this can be easily done by modulating the amount of liquid API dispensed on the film. The mesh size and screen diameter of the nozzle can also determine the number of doses printed on one film and with fairly good uniformity. Although the above-mentioned advantages and potential of drug printing can be partially addressed, there is still much work to be done before routine incorporation of drug printing in treatment options [21, 22].

Case Studies

Among others, pharmaceutical dosage forms such as tablets, are gaining in importance, as they not only represent the most predominant dosage form, but also serve as easy-to-handle carriers of active pharmaceutical ingredients. Lately, there is a demand for more efficient and sophisticated formulations of pharmaceutical-solid dosage forms. Consequently, new formulations processes are in demand to render existing technologies more cost efficient or contribute to new developments in formulation technologies that provide a better tailored quality of solid drug formulations. New as many existing formulations technologies are based on mass producing processes, meaning that the invention of such a process will surely be beneficial for many formulations. But even sophisticated formulations technologies are premature if they cannot be transferred to industrial scales. With the following three examples dealing with in situ coating, freeze casting, and protein-based biocomposites, developments are presented that fulfill the two previous requests. The first example targets the coating of tablets with organic solvents to generate a co-crystal layer of indomethacin and malonic acid in a prespecified thickness. The precursors are formulated entirely in the dry powder state, avoiding any additional processing steps. Besides that, the gain of economic efficiency, an advantage of such an in-situ coating design as compared to conventionally coated tablets is the tailorable release rate through crystalline continuous diffusion. Aqueous coatings for faster release rates would tend to swell, thus rendering it more difficult to predict the relevant properties. Furthermore, liberating a well-defined core after dissolution of the coating could be of interest, too. All in all, the in-situ coating fulfills major requirements concerning drug delivery control and economic efficiency in pharmaceutical formulation technologies [23, 24].

Collaborative Efforts

The principles and practices of collaborative platforms should be adapted to the specifics of innovations, challenges, stakeholders and organisations, allowing for flexibility in the way they are implemented, but also common features and structures that support transdisciplinarity issues and communities across innovations. Overstating the potential for open innovation can lead to sub-optimal innovation platforms or hindering dysfunctional ones. Effective platforms for value generation to patients using advanced therapies can require a million EUR investment to take shape early on and many more million EUR together before success can be ensured. In the absence of success, value generation will be zero and expenditure will be wasted. In addition to the technical details, a range of factors such as competition, fear of sharing with competitors and governments, diverging interests and cultures may hinder success. A balanced government based on the transparency of rules and procedures, equal opportunities to benefit from initiatives, a competitive focus on value generation and decentralised control are key requirements for successful partnerships of balanced governance. The complexity and uncertainties of the expected advances in the collaboration could lead to the inefficient use of resources, as platforms can become too rigid and focused on narrow pre-established purposes. These should not impose pre-established structures but rather respond to emerging challenges and opportunities giving the initiative to the stakeholders beyond the inventors. Roads ahead are likely to shift, opening up new opportunities and bringing new stakeholders in and thus evolution is required. Platforms can help translate medicines development taking years into decades, following longer, more prescriptive and sometimes more punitive processes than drugs. Labeling a drug, a step most familiar to developers, that can take fourteen years to achieve, to define what can go on a market and what use can be made of it is more complex for advanced therapies. Defining what is a result of the therapy and assessing this sufficiently to enable an informed judgment for the expected value of the therapy is a challenge that platforms can help meet early on. Help ensuring comparators able to inform the development of individualised drugs is welcome [25-28].

CONCLUSION

Personalized medicine and individualized drug formulations represent a critical evolution in pharmaceutical science aimed at addressing the genetic and physiological variability among patients. Technologies such as 3D and emerging 4D printing are redefining drug manufacturing, offering tailored therapies that align with patient-specific needs. Pharmacogenomics further enhances treatment precision by enabling drug selection and dosing based on genetic profiles. Despite significant promise, the field faces challenges related to regulatory approval, economic scalability, ethical considerations, and technological integration into clinical practice. As innovations continue to evolve, ensuring patient-centered care, equitable access, and rigorous regulatory standards will be vital for the widespread adoption of individualized therapies. The future of healthcare will increasingly depend on these personalized approaches, ultimately improving patient outcomes and healthcare system efficiency.

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